

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****7 CFR Part 335**

[Docket No. 93-026-1]

RIN 0579-AA61

**Introduction of Nonindigenous Organisms**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule and notice of public hearings.

**SUMMARY:** We are proposing to establish comprehensive regulations governing the introduction (importation, interstate movement, and release into the environment) of certain nonindigenous organisms. This action appears to be necessary because the plant pest regulations under which the movement of certain nonindigenous organisms are currently regulated do not adequately address the introduction of nonindigenous organisms that may potentially be plant pests. The proposed regulations would provide a means of screening certain nonindigenous organisms prior to their introduction to determine the potential plant pest risk associated with a particular introduction.

**DATES:** Consideration will be given only to comments received on or before March 27, 1995. We will also consider comments made at public hearings to be held on March 6, 1995, in Kansas City, MO; March 7, 1995, in Sacramento, CA; and March 10, 1995, in Washington, DC. Each public hearing will begin at 10 a.m. and is scheduled to end at 5:00 p.m.

**ADDRESSES:** Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, P.O. Drawer 810, Riverdale, MD 20738. Please state that your comments refer to Docket No. 93-026-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room. The public hearings will be held at the following locations:

1. Kansas City: Kansas City Airport Marriott, 775 Brasilia Avenue, Kansas City, MO;

2. Sacramento: Holiday Inn Holidome, 5321 Date Avenue, Sacramento, CA;
3. Washington, DC: Jefferson Auditorium, U.S. Department of Agriculture, South Building, 14th Street and Independence Avenue SW., Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Dr. Matthew H. Royer, Chief Operations Officer, Biological Assessment and Taxonomic Support, Operational Support, Plant Protection and Quarantine, APHIS, USDA, P.O. Drawer 810, Riverdale, MD 20738. The telephone number for the agency contact will change when agency offices in Hyattsville, MD, move to Riverdale, MD, during February. Telephone: (301) 436-8896 (Hyattsville); (301) 734-8896 (Riverdale).

**SUPPLEMENTARY INFORMATION:****Public Hearings**

Public hearings are scheduled to be held in Kansas City, MO, on March 6, 1995; in Sacramento, CA, on March 7, 1995; and in Washington, DC, on March 10, 1995.

A representative of the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), will preside at each public hearing. Any interested person may appear and may be heard in person, by attorney, or by other representative. Written statements may be submitted and will be made part of the meeting record. Persons who wish to speak at a public hearing will be asked to provide their name and organization. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing.

Each public hearing will begin at 10 a.m. and is scheduled to end at 5 p.m., local time. However, the hearing may be terminated at any time after it begins if all persons desiring to speak have been heard. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

The purpose of the hearings is to give interested persons an opportunity for the oral presentation of data, views, and arguments. Questions about the content of the proposed rule may be part of the commenters' oral presentations. However, neither the presiding officer nor any other representative of APHIS will respond to the comments at the hearing, except to clarify or explain provisions of the proposed rule.

**Background**

The Secretary of Agriculture has authority under the Federal Plant Pest

Act, as amended (7 U.S.C. 150aa through 150jj) and the Plant Quarantine Act, as amended (7 U.S.C. 151 through 164a, 167) to regulate the movement of articles to prevent the introduction and dissemination into and within the United States of plant diseases, injurious insects, and other plant pests, hereinafter referred to as plant pests. APHIS has been delegated the authority to administer these and other related statutes and has promulgated regulations implementing these statutes in 7 CFR chapter III.

Many of the regulations in 7 CFR chapter III are designed to protect against the inadvertent dissemination of plant pests that may be associated with certain plants, plant parts, or other articles. For example, the foreign quarantine notices in 7 CFR part 319 contain regulations that restrict the importation and entry of, among other things, foreign cotton, sugarcane, fruits and vegetables, and coffee in order to prevent the entry of plant pests.

The regulations in 7 CFR chapter III also provide for the issuance of permits for the movement of plant pests into (importation) or through (transit shipment) the United States, or interstate. A person may apply to APHIS for a permit using the application process set forth in the plant pest regulations in 7 CFR 330.200. Under those regulations, APHIS will review an application and make a determination as to whether the movement of the plant pest can be accomplished in a manner that will prevent its dissemination. If adequate safeguards can be put into place to prevent the dissemination of the plant pest, APHIS may issue a permit for the movement into or through the United States, or interstate, of the plant pest.

The scope of the plant pest regulations in 7 CFR 330.200 is limited to the movement of known plant pests; the movement of nonindigenous organisms not known to present a plant pest risk, as well as the release of such organisms into the environment, are not addressed. A report on nonindigenous species prepared by the U.S. Congress' Office of Technology Assessment (OTA), "Harmful Non-Indigenous Species in the United States," (OTA-F-565, Washington, DC; U.S. Government Printing Office, September 1993) (referred to below as the OTA report) recommends that APHIS more closely examine any proposed introduction (importation, interstate movement, or release into the environment) into the United States of a nonindigenous organism. The OTA report cited losses in the billions of dollars that can be attributed to the negative effects of

certain nonindigenous organisms. As U.S. agriculture's "first line of defense," we believe that APHIS must supplement its current regulations to prevent or minimize the potential problems presented by the introduction of nonindigenous organisms whose plant pest status is unknown. Therefore, we are proposing to establish comprehensive regulations governing the introduction of those nonindigenous organisms that we have reason to believe may be plant pests or may result in the introduction or dissemination of plant pests.

In our proposed regulations, a nonindigenous organism is defined as any organism proposed for introduction into any area of the United States beyond its established range. Therefore, an organism does not have to be from another country to be considered nonindigenous; an organism that has an established range only in one part of the United States would be considered nonindigenous in another part of the United States.

The proposed regulations would not eliminate the plant pest regulations in 7 CFR 330.200. Those regulations would remain in place to govern the importation and interstate movement of known plant pests, both indigenous and nonindigenous. The proposed regulations would allow APHIS to examine certain nonindigenous organisms proposed for introduction to determine whether those nonindigenous organisms are plant pests or constitute a risk of the introduction or dissemination of plant pests. The proposed regulations would impose conditions on the introduction of those nonindigenous organisms in order to prevent plant pest dissemination. Under the proposed regulations, persons wishing to import or move interstate a regulated nonindigenous organism would first have to apply for a permit from APHIS. The proposed regulations would also contain specific provisions regarding permits for the release of certain nonindigenous organisms, such as pollinators or biological control agents, into the environment.

It is the USDA's position that the provisions of the proposed rule that would require a permit for the release of a nonindigenous organism into the environment are consistent with the Federal Plant Pest Act and the Plant Quarantine Act and are a reasonable construction of the Secretary of Agriculture's statutory authority under those acts. The Federal Plant Pest Act and the Plant Quarantine Act authorize the Secretary of Agriculture to take certain actions to prevent the

introduction into and dissemination within the United States of plant pests.

### Scope

Our authority to regulate nonindigenous organisms is based on there being reason to believe that such organisms may be plant pests or may result in the introduction or dissemination of plant pests. Therefore, any nonindigenous organisms that we propose to regulate would necessarily have to fall within one of the categories of organisms included in the definition of a plant pest or would have to present a risk of introducing or disseminating a plant pest. The Federal Plant Pest Act defines a *plant pest* as "any living stage of: Any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants."

Within the categories of organisms addressed above, there are several nonindigenous organisms that are already regulated by APHIS elsewhere in its regulations and would not, therefore, be included in the scope of the proposed regulations. Those organisms are addressed below in the discussion of proposed § 335.2.

### Proposed Regulations

The proposed regulations contain nine sections:

- § 335.1 Definitions.
- § 335.2 Regulated organisms.
- § 335.3 General restrictions on the introduction of regulated organisms.
- § 335.4 Permits for the introduction of regulated organisms.
- § 335.5 Nonindigenous organisms exempted from regulation under this part.
- § 335.6 Conditions for the introduction of regulated organisms.
- § 335.7 Facilities for the containment of regulated organisms.
- § 335.8 Container requirements for the movement of regulated organisms.
- § 335.9 Costs and charges.

Each of these sections is discussed in detail below.

#### Definitions (§ 335.1)

In proposed § 335.1, we define terms used in the regulations. Several of these terms—*Administrator*, *Animal and Plant Health Inspection Service (APHIS)*, *APHIS inspector*, *import*, *interstate*, *introduce (introduction)*,

*move (moving, movement)*, *permit*, *person*, *port of first arrival*, *State*, and *United States*—are terms used by APHIS elsewhere in its regulations in 7 CFR chapter III and 9 CFR chapter I. The remaining terms, as they apply to our proposed regulations, are explained below.

We would define *nonindigenous organism* as "any organism proposed for introduction into any area of the United States beyond its established range." This definition would place the primary focus on whether the area into which an organism would be introduced is within or outside of the organism's *established range* (which we would define as "the area in which a species maintains a self-sustaining, free-living population").

To identify the organisms covered by the proposed regulations, the term *regulated organism* would be defined as "any living stage of any nonindigenous organism belonging to the taxa listed in § 335.2(a) that is not listed in § 335.2(b) or exempt in accordance with § 335.5." The list in § 335.2(a) is set forth later in this proposed rule.

We would define *environment* as "all land, air, and water; and all living organisms in association with land, air, and water." As part of our review of permit applications, we must consider a regulated organism's effects on the environment within its established range and its potential to affect the environment in the area into which its introduction is proposed. The proposed definition, therefore, takes into account those elements of what is commonly considered to be "the environment" that could be affected by the introduction of a regulated organism.

*Established* would be defined as "the condition of a species that has formed a self-sustaining, free-living population at a given location." We are proposing to require that a person seeking a permit furnish, as part of a permit application, information pertaining to a regulated organism in its established range. This definition would help to clarify the information to be included in an application.

*Plant* would be defined as "any stage of any member of the plant kingdom including, but not limited to, trees, plant tissue cultures, plantlet cultures, pollen, shrubs, vines, cuttings, grafts, scions, buds, roots, seeds, cells, tubers, and stems." *Plant product* would be defined as "any processed or manufactured plant or plant part." These definitions are based on our statutory authority under the Federal Plant Pest Act, as amended, and the Plant Quarantine Act, as amended.

We would use the definition provided for *plant pest* in the Federal Plant Pest

Act: "Any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts of parasitic plants, viruses, or any organisms similar to or allied with any of the organisms previously identified in this definition, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or plant parts, or any processed, manufactured, or other products of plants."

We would define *release into the environment* as "the use of a regulated organism outside the constraints of physical confinement." Given the nature of many regulated organisms, we believe that it is necessary to treat any use of a regulated organism outside of the constraints of physical confinement, such as those found in a laboratory or greenhouse, as a release into the environment.

#### *Regulated Organisms (§ 335.2)*

Paragraph (a)(1) of proposed § 335.2 contains a list of taxonomic groups that include known plant pest species. We have reason to believe that other species within those taxonomic groups may also be plant pests; therefore, we believe that nonindigenous organisms within those taxonomic groups should be evaluated prior to their introduction into the United States. The list was drawn from a similar list contained in 7 CFR part 340 and was developed based on APHIS' experience with issuing plant pest permits. (The list in proposed § 335.2(a)(1) differs from the list in 7 CFR part 340 in two respects. First, parasitic weeds of the species *Alectra* are included on the list in 7 CFR part 340 but have been omitted from the list in proposed § 335.2(a)(1) because *Alectra* spp. are listed noxious weeds in 7 CFR 360.200. The second respect in which the two lists differ is that the list in proposed § 335.2(a)(1) contains additional taxonomic groups under the class Insecta. These additional groups, which are listed below, were included on the list in proposed § 335.5(a)(1) based on APHIS' experience with issuing plant pest permits:

- Family Aphelinidae
- Family Braconidae
  - Genus Perilitus
- Family Diapriidae
  - Genus Ismarus
- Family Encyrtidae
- Family Eulophidae
- Family Ichneumonidae
  - Subfamily Cryptinae
  - Subfamily Diplazontinae
  - Subfamily Gelinae
  - Subfamily Mesochorinae

- Subfamily Ephialtinae
- Family Pteromalidae
- Family Scelionidae
  - Genus Gryon
  - Genus Scelio
- Family Signiphoridae
- Family Trichogrammatidae

If the list in proposed § 335.2(a)(1) is adopted and a person believes that an organism should be added to the list, that person could petition APHIS for a change in the regulations under the Administrative Procedure Act (5 U.S.C. 553(e)) and the USDA's regulations in 7 CFR part 1.

The taxonomic scheme used in proposed § 335.2(a)(1) is a five-kingdom system, found in S.P. Parker's "Synopsis and Classification of Living Organisms" (McGraw Hill, 1984). Within each taxon, all nonindigenous species are regulated organisms, unless there are taxa of lower rank specifically listed, in which case only those specifically listed, lower-ranked taxa are regulated organisms. Other classified organisms not listed are not regulated organisms.

We believe that organisms that are currently unclassified or whose classification is unknown should be evaluated prior to their introduction into the United States because of the possibility that the organisms contain plant pests or are themselves plant pests; therefore, such organisms would also be regulated organisms under § 335.2(a)(2).

As mentioned above, the proposed regulations would not supplant our existing plant pest regulations in 7 CFR 330.200. Additionally, there are other organisms covered elsewhere in existing regulations that would also remain regulated under the existing regulations. To make that clear, paragraph (b) of proposed § 335.2 would specify that the following categories of organisms would continue to be regulated under their existing regulations: Live bees other than honeybees of the genus *Apis* regulated under 7 CFR 319.76; plant pests regulated under 7 CFR 330.200; live honeybees of the genus *Apis* regulated under 7 CFR part 322; organisms genetically engineered through recombinant DNA techniques regulated under 7 CFR part 340; noxious weeds regulated under 7 CFR part 360; organisms and vectors that may introduce or disseminate contagious animal diseases regulated under 9 CFR part 122; and etiologic microorganisms that cause disease in humans (including bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, arthropods, parasites, and the hosts and vectors that may carry these etiological microorganisms) that are regulated by

the Centers for Disease Control and Prevention under 42 CFR part 71, unless the microorganism, host, or vector could also be a plant pest.

#### *General Restrictions on the Introduction of Regulated Organisms (§ 335.3)*

This section of the proposed regulations prohibits the introduction of any regulated organism unless the regulated organism is introduced in accordance with the proposed regulations. This means that a regulated organism may not be imported, moved interstate, or released into the environment unless APHIS has given its authorization to do so. Under the proposed regulations, that authorization would entail the issuance of a permit for the introduction in accordance with proposed § 335.4. The permit application process is discussed in detail below.

Section 335.3 of the proposed regulations also provides that any introduction of a regulated organism that is not in compliance with the provisions of the proposed regulations makes that regulated organism subject to destruction, disposal, or the remedial measures that the Administrator determines to be necessary to prevent a plant pest from being introduced into, or disseminated within, the United States.

We believe that these restrictions on the introduction of regulated organisms are necessary to prevent the introduction and dissemination within the United States of plant pests.

#### *Permits for the Introduction of Regulated Organisms (§ 335.4)*

Section 335.4 of the proposed regulations sets forth the proposed process by which a person may obtain a permit from APHIS for the introduction of a regulated organism. The section also sets forth the procedure that would be followed by APHIS in response to the receipt of a permit application and the appeal procedure that would be available in the event of APHIS' denial of a permit application or revocation of a permit.

Proposed paragraph (a) provides that an application for a permit must be submitted to the Administrator in care of Biological Assessment and Taxonomic Support (BATS), which is the staff within APHIS that would be responsible for the processing of permit applications submitted under the proposed regulations. The application would have to state the type of permit being requested by the applicant (import, interstate movement, or release into the environment). Although the mailing address of BATS is provided in

proposed paragraph (a), the proposed regulations would not necessarily require that an application be submitted through the mail. By not specifically requiring that an application be made in written form through the mail, we are intentionally leaving open the possibility that a person could submit an application using other means, such as via facsimile machine or in an electronic medium compatible with APHIS equipment.

Proposed paragraph (a)(1) provides that a person may apply for a permit for the importation or interstate movement of regulated organisms within a taxon of a higher level than species (genus, family, order, class, phylum). Because research is not always confined to a single organism, or even to an identified group of organisms, the issuance of such a permit would give researchers the ability to import or move interstate a wide range of regulated organisms without having to submit a permit application for each species or strain of regulated organism. We believe that we could assure the prevention of plant pest dissemination during the importation or interstate movement of even a wide range of regulated organisms by assigning specific conditions that would apply to the importation or interstate movement of all regulated organisms covered by the permit. The conditions that would be assigned to the permit would be designed to ensure that there is an appropriate level of biosecurity, which would be determined by the biological characteristics of the entire taxon. Because the range of organisms that might be included in a permit could be quite broad, the assigned safeguards may be more stringent than those that might be assigned to a single organism within the same taxon.

Proposed paragraph (a)(2) contains provisions for the identification of trade secret or confidential business information (CBI). As set forth in the USDA's regulations regarding the handling of information from private businesses (see 7 CFR 1.11), the USDA is responsible for making the final determination with regard to the disclosure of information designated CBI, but the policy of the USDA is to obtain and consider the views of the submitter and to provide the submitter the opportunity to object to the disclosure of CBI.

Under proposed paragraph (a)(2), if an application contained any information deemed to be CBI, we would require that two copies of the application be prepared. Each page of one copy would have to be marked "CBI Copy" and have all CBI designated as such. The second

copy would be required to have all designated "CBI Deleted" and would be marked "CBI Deleted" on each page of the copy.

Proposed paragraph (a)(3) provides that an application for a permit for the importation or interstate movement of a regulated organism must be received by the Administrator at least 30 days prior to the date of the proposed importation or interstate movement and that an application for the release into the environment of a regulated organism must be received by the Administrator at least 120 days prior to the date of the proposed release. The 30- and 120-day time periods referred to in proposed paragraph (a)(3) are necessary to ensure that APHIS has adequate time to review applications for permits.

Proposed paragraph (a)(4) provides that, after receiving an application, APHIS would conduct a review to determine whether the application contains all of the information required by proposed § 335.4. This review would be completed within 15 days of our receipt of an application for importation or interstate movement, and within 30 days of receiving an application for release into the environment. Upon completion of the review to determine whether the application contains all of the information required by proposed § 335.4, we would inform the applicant of the date that the application was received, which would be the date that the review period had commenced, or, if the application is incomplete, what additional information is needed. Once an application is complete, APHIS would commence its review of the application. A copy of the application marked "CBI Deleted" or "No CBI" would be forwarded to the State department of agriculture in the State where the introduction is planned so that the State would have an opportunity to review the application and convey any comments to APHIS.

In addition to that State review, which, unless waived by an individual State, would be conducted on all applications for the importation, interstate movement, or release into the environment of a regulated organism, there are several Federal agencies other than APHIS that have authority over the release into the environment of certain regulated organisms. (Within the USDA, there are the Agricultural Marketing Service, the Agricultural Research Service, the Cooperative State Research Service, the Forest Service, and the Extension Service; outside the USDA are the Fish and Wildlife Service, the National Oceanic and Atmospheric Administration, the Department of Defense, the Environmental Protection

Agency, the Centers for Disease Control and Prevention, the Customs Service, the U.S. Coast Guard, the U.S. Army Corps of Engineers, and the Drug Enforcement Agency.) These agencies may be consulted as part of our 30-day review to determine whether the application contains all of the information required by proposed § 335.4. There also may be instances when consultation with another Federal agency would be required. For example, APHIS would have to consult with the Fish and Wildlife Service if APHIS determined that a regulated organism proposed for release into the environment may have an effect on a threatened or endangered species. Because another agency would be involved, APHIS would no longer have full control over the review of an application and could not, therefore, be certain that the review would be completed in the specified 120-day review period. In such cases, the applicant would be notified, in writing, of the need for consultation and informed that the review period may extend beyond the specified 120 days.

When an application contains all the information required by proposed § 335.4 and outside consultation is not required, we believe that the applicable 30- or 120-day review period is sufficient for APHIS to thoroughly examine all aspects of a particular proposed introduction of a regulated organism. Based on our past experience in processing applications, we anticipate that, in many cases, action on a permit application would be completed in less time. When sufficient applicable data are available from previously issued permits, APHIS may be able to complete its review of a permit application in appreciably less time than the applicable 30- or 120-day review period.

Paragraphs (b) through (e) of proposed § 335.4 contain the data requirements that would have to be met for an application to be deemed complete. Paragraph (b) contains data elements that would apply to all permit applications; paragraphs (c), (d), and (e) contain specific additional data elements that would be required for applications for importation, interstate movement, and release into the environment, respectively.

Except for those elements that are administrative in nature, the proposed data elements would be a means by which we could assess the plant pest and environmental risks involved in a proposed introduction. A regulated organism of concern would fall into one of the following categories: (1) An organism of foreign origin that is not

present in the United States; (2) an organism of foreign origin that is present in the United States but is capable of further expansion beyond its present established range; and (3) an organism of foreign origin that has reached its full range of potential establishment in the United States but is sufficiently biologically different from the organism that is present in the United States to warrant concern. In each of these three categories, the regulated organism may be also of concern if it can vector a foreign plant pest that also falls into one of the three categories. The criteria we may use to further determine whether a regulated organism in one of the above categories warrants concern may be whether the organism causes an increase in the population of a plant pest or whether the organism causes injury or disease to plants.

We believe the information that would be required in a permit application is necessary for APHIS to be able to gain a clear understanding of the potential plant pest risk and environmental effects of the introduction for which a person is seeking a permit. The specific data requirements are discussed in detail below.

The first item that would be required under proposed paragraph (b) for all permit applications would be the name, address, telephone number, and facsimile number of the person seeking a permit. This information is necessary because the permit will be issued to that person, and we will likely need to contact that person during the application review process.

We would then require several items that would serve to identify the regulated organism and describe its biology. To that end, we would require:

1. *The scientific name, common name, and any other information that serves to identify the regulated organism as specifically as possible (including the subspecies, race, and strain of the regulated organism) and a description of the methods used to establish the identity of the regulated organism.* The accurate identification of a regulated organism is a necessary first step in APHIS' review of an application, and knowing what methods were used, including consultation with experts, to identify the regulated organism would enable APHIS to evaluate the accuracy of the identification. If new techniques or information become available that allow the regulated organism to be more accurately identified, APHIS may need this information from the applicant in order to fairly review the application and assess the plant pest and environmental risks associated with the

proposed introduction of the regulated organism. This type of information would also help APHIS to verify whether the application is complete by comparing information provided in the application to that available in the literature and other sources.

2. *A description of the measures that have been taken to establish that the regulated organism and any material associated with the introduction of the regulated organism do not contain any organisms not identified in the permit application.* This information would be used by APHIS to address the issue of purity as it applies not only to the regulated organism itself, which may have hyperparasites or other organisms, for example, but also as it applies to any material, such as packaging or host material, associated with the introduction of the regulated organism. By knowing what organisms will be associated with the regulated organism, APHIS can more comprehensively determine the plant pest risk associated with the regulated organisms and assign appropriate conditions on the permit.

3. *The intended use of the regulated organism.* This information would apprise APHIS of the materials, methods, or procedures to be used in the intended experimental, commercial, or other uses of the regulated organism. That knowledge would be used by APHIS to assess plant pest risk, determine conditions necessary to mitigate the risk, and come to a decision regarding the issuance or denial of a permit. Additionally, pursuant to the provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA), we will consider, during our analysis, the potential beneficial or harmful effects that a regulated organism could have on the environment, such as the effects that a regulated organism used as a biological control agent could have on its target and nontargets.

4. *A description of the life cycle, biology, and ecology of the regulated organism.* Understanding a regulated organism's potential for survival, establishment, and dispersal would enable APHIS to determine the plant pest risk associated with the regulated organism. A description of the biological characteristics of the organism would be of use to APHIS during its review of the permit application, especially if relatively little is known about the organism.

5. *Whether the regulated organism has been genetically modified (if so, include a description of the genetic modification).* If the regulated organism has been genetically modified through sexual recombination and selection for

traits not typical of the organism in nature, through induced mutation and selection for special traits, or through other classical techniques, APHIS would need a description of the modification in order to assess the biology of the modified regulated organism insofar as it differs from that of an unmodified organism of the same species. If, on the other hand, recombinant DNA techniques had been used to effect a modification, BATS would refer the applicant to the Biotechnology Permits staff of Biotechnology, Biologics, and Environmental Protection, which handles permits for genetically engineered organisms.

6. *The country and locality where the regulated organism was originally collected from nature, and the countries and localities where the regulated organism has been propagated and maintained since its collection.* When assessing plant pest risk, APHIS would consider the conditions in the country or countries in which a regulated organism was collected, propagated, and maintained. This information would be used by APHIS to determine whether sufficient safeguards are in place to prevent contamination of the regulated organism by other organisms. In addition, an organism may genetically vary from area to area, so this information may have bearing on APHIS' determination of plant pest risk.

7. *The established range of the regulated organism in the United States.* If the regulated organism is already established in one or more areas of the United States, this information would be used to determine the plant pest and environmental risks to areas of the United States in which the organism does not already occur, and to identify circumstances under which consultation with specific States and other parties may be necessary before assigning conditions for the movement or release of a regulated organism that is established within the United States.

We would also require information relating to details of the proposed introduction:

8. *The number of specimens or units of the regulated organism to be introduced.* The scale of the introduction would be one factor considered when assessing the possible plant pest risk associated with a regulated organism. APHIS would consider whether the destination facility listed on the application is equipped to handle any large quantities of a regulated organism. The safeguards assigned as conditions of a permit would have to be adequate to mitigate that risk.

9. *A description of any host material, substrate, medium, or organism that will accompany the regulated organism.*

There may be times when the material accompanying a regulated organism is itself regulated or restricted, such as a nonindigenous rust fungus on plants of the genus *Berberis*. (The interstate movement of certain *Berberis* species is restricted under 7 CFR 301.38.) An accurate description of the material accompanying a regulated organism would enable APHIS to ascertain the purity of the regulated organism and to decide whether the requirements of other regulations needed to be met before a permit could be issued.

The final three data requirements of paragraph (b) direct the person applying for a permit to answer the additional questions in paragraph (c) if applying for a permit to import a regulated organism, paragraph (d) if applying for a permit to move a regulated organism interstate, and paragraph (e) if applying for a permit to release a regulated organism into the environment.

A person applying for a permit to import a regulated organism would have to provide the following seven data elements in proposed paragraph (c) in addition to the data elements required by paragraph (b):

10. *The country and locality from which the regulated organism will be exported to the United States.* When assessing plant pest risk, APHIS would consider the conditions in the country and locality in which a regulated organism was maintained. This information would be used by APHIS to determine whether sufficient safeguards are in place to prevent contamination of the regulated organism by other organisms.

11. *The address, telephone number, and facsimile number of the person in the exporting country from whom the regulated organism will be received.* This information would be used by APHIS to assess whether sufficient safeguards are in place in the exporting country to prevent contamination of the regulated organism by other organisms. APHIS would need to know whether a regulated organism is coming from, for example, some type of commercial or scientific establishment or directly from nature in order to accurately assess all factors affecting the purity of an organism.

12. *The port of first arrival in the United States through which the regulated organism is intended to be imported.* Section 335.6 of the proposed regulations would require that all regulated organisms imported into the United States be imported through a port of first arrival that has a plant

inspection station. The answer to this question would allow APHIS to ensure that the person importing a regulated organism planned to use a plant inspection station and would give APHIS the opportunity to give advance notice to personnel at the port of first arrival as a means of facilitating handling of the regulated organism.

13. *The address (including the county), telephone number, and facsimile number of the facility to which the regulated organism will be delivered.* Under § 335.6 of the proposed regulations, all regulated organisms imported into the United States could be moved only to the destination listed on its permit. APHIS would need to know the destination of the organism so that the facility could be inspected to verify whether the conditions at the facility meet the requirements of proposed § 335.7.

14. *A detailed description of the procedures, processes, and safeguards that will be used in the destination facility to prevent the escape and dissemination of the regulated organism and any material accompanying the regulated organism.* This information is necessary for APHIS to assess whether the conditions at the facility in which the regulated organism would be held meet the requirements of proposed § 335.7.

15. *The means by which the regulated organism will be imported into the United States (air mail, air freight, baggage, or motor vehicle).* This information would be provided to an APHIS inspector at the port of first arrival to facilitate the entry of a regulated organism.

16. *The planned date(s) of the importation of the regulated organism.* The planned dates of importation would be needed so APHIS could verify that a regulated organism was received at its destination. Also, there may be circumstances when APHIS would recommend or assign dates of importation to help minimize the risk of spread in the event of an escape of the regulated organism.

A person applying for a permit to move a regulated organism interstate would have to provide the six data elements in paragraph (d) in addition to the data elements required by paragraph (b). These six data elements are:

17. *The State and locality from which the regulated organism will be moved interstate.* When addressing plant pest risk, APHIS would consider the conditions in the State and locality in which a regulated organism was located. This information would be used by APHIS to determine the plant pest risk posed by the regulated organism.

18. *The address, telephone number, and facsimile number of the person in the originating State from whom the regulated organism will be received.* For interstate movement, the proposed regulations in § 335.6 would require that a regulated organism be moved interstate only to the destination listed on the permit. Knowledge of the location from which the regulated organism is to be moved would help APHIS to determine whether conditions at the facility in which the regulated organism would be held after interstate movement meet the requirements of proposed § 335.7.

The remaining four data requirements for paragraph (d) are the same as the final four data requirements in paragraph (c), and would serve the same purpose in APHIS' review of the application.

A person applying for a permit to release a regulated organism into the environment would have to address the data elements in proposed paragraph (e) in addition to the data elements already required by proposed paragraph (b). The effects of releasing a regulated organism into the environment generally have the potential to be much more far-reaching than those associated with importation and interstate movement. When considering an application for an environmental release, APHIS must consider the plant pest risk associated with the release and the effects the release could have on the environment as a whole. This means that the provisions of statutes such as the Endangered Species Act and NEPA would have to be considered.

As discussed previously, there are several agencies other than APHIS that may have an interest in the release into the environment of regulated organisms and that may be consulted as part of our 30-day review to determine whether the application for a permit to release a regulated organism into the environment contains all the data required by proposed § 335.4. The additional requirements of paragraph (e) would, therefore, be used to help determine what statutes might apply to the proposed release into the environment and what agencies APHIS might have to contact during its review of the application. We envision that State regulatory officials will play a significant role in providing environmental and ecological data regarding the location where the regulated organism is to be released, and otherwise assist in the enforcement of the Federal regulations on a cooperative basis.

The additional data requirements for applications to release a regulated organism into the environment are:

19. *The purpose of the release into the environment of the regulated organism.* This information would be used by APHIS during its preparation of an environmental assessment.

20. *The anticipated date(s) of the release into the environment of the regulated organism.* This information would be used to determine the possible effects on nontarget species that may be particularly susceptible or exposed to the regulated organism at the time of its release into the environment.

21. *A description, including methods of release and release site(s), of the intended release into the environment of the regulated organism.* The method of release may impact the risk presented by the regulated organism to the environment or plants, and APHIS may specify conditions on a permit to mitigate that risk. The locations of planned release sites would be needed to facilitate the evaluation of future applications for releases of regulated organisms into the environment at the same sites in the future.

22. *A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment.* This data element would be used to help APHIS evaluate whether sufficient testing and review to determine the potential environmental effects of a regulated organism had been conducted prior to issuing a permit for release into the environment. If the regulated organism is to be used as a biological control agent, any testing and review that has been conducted to assess the effects of the biological control agent on nontarget organisms must be described.

23. *The effect of the regulated organism on the environment in its established range.* This information would be used to help APHIS evaluate the anticipated effects, including potential effects on threatened and endangered species, of releasing the regulated organism into the environment. These effects may include destruction or lessening of the aesthetic, recreational, or commercial value of the environment, including threatened and endangered species. If APHIS determined that there would be negative effects on the environment or on threatened or endangered species, APHIS would report that information to the proper Federal authorities.

24. *The host specificity of the regulated organism under both artificial and natural conditions.* This information would help focus APHIS' investigation of the nontarget effects of

the regulated organism. Of particular interest to APHIS would be the regulated organism's potential effects on any biological control agents that already might be in use in the area of the proposed release. This data element, as well as those data elements dealing with the regulated organism's effects on nontargets and the environment, would help APHIS address that concern.

25. *References to any published and unpublished documents that support the information required by paragraphs (e)(4), (e)(5), and (e)(6) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application.* If the application contains information that is supported by available literature, it would be useful for APHIS to review that literature to assess plant pest risk and potential environmental effects. APHIS could reasonably expect to have access to any published material cited in the application, but the unpublished documents available to the applicant must be attached to the application.

#### *Facility and Release Site Inspection*

Paragraph (f) of proposed § 335.4 would provide that the Administrator may inspect the facility into which a regulated organism proposed for importation or interstate movement would be moved to determine whether the procedures, processes, and safeguards at the facility meet the requirements of proposed § 335.7. Similarly, the Administrator would be allowed to inspect the site where a regulated organism would be released into the environment so that a determination could be made as to the effects on the environment of the proposed release of the regulated organism.

#### *Administrative Action on Applications*

Paragraph (g) of proposed § 335.4 would provide that a permit would be either issued or denied upon completion of APHIS' review of the application.

If a permit is issued, it would be numbered and would specify the conditions that would apply to the introduction of the regulated organism. There may be considerations based on the particular characteristics of a regulated organism that APHIS would take into account when determining the length of time for which a permit would be valid. Thus, to allow both APHIS and the permittee the greatest degree of flexibility, all permits would not be valid for the same predetermined length of time; rather, the length of a permit's validity would be based on the circumstances of that particular

introduction. Therefore, we are proposing that a permit could be valid for as long as 10 years following the date of issuance, unless the permit was revoked in accordance with proposed § 335.4(h). The expiration date would be specified on the permit.

Proposed paragraph (g)(2) states that if a permit is denied, the applicant would be promptly informed, in writing, of the reasons the permit was denied and given the opportunity to appeal the denial in accordance with proposed § 335.4(h).

A permit application would be denied to an applicant from whom a permit had been revoked within the past 12 months due to the failure of the applicant or the applicant's agents or employees to comply with the proposed regulations or any condition specified on the permit, unless the permit has been reinstated upon appeal. We believe that this provision is necessary to ensure that applicants who have had a permit revoked for cause are not able to immediately reapply for a new permit. We believe this would discourage violations of the regulations and would help advance the effectiveness of the permit system as a means of excluding plant pests from the United States.

Proposed paragraph (g) would further provide that a permit would be denied if an APHIS inspector is not allowed to inspect the facility into which a regulated organism proposed for importation or interstate movement would be moved or the site where a regulated organism is proposed to be released into the environment. In order to prevent or mitigate the potential plant pest risks that may be associated with an introduction, we believe that it is essential that APHIS have the opportunity to assess the conditions under which a regulated organism would be held after movement or released into the environment.

A permit would also be denied if the Administrator determines, based on a review of the available information, that the introduction of the regulated organism would present a significant risk of plant pest dissemination and that no adequate safeguards could be arranged to mitigate the risk presented by the proposed introduction.

#### *Denial or Revocation of Permit; Appeals*

Proposed paragraph (h) would provide that APHIS may revoke a permit that has already been issued if the conditions of the permit or any part of the proposed regulations were violated by the person to whom the permit was issued, or his or her agents or employees. We believe that the proposed regulations are necessary to

ensure that the introduction of regulated organisms would be conducted under conditions that prevent the introduction and dissemination of plant pests; that desired level of safety could not be reached if a regulated organism was introduced contrary to the conditions of the permit or the proposed regulations. If a person believed that a permit was wrongfully revoked or a permit application was wrongfully denied, that person could appeal to the Administrator, in writing. The appeal process is set forth in paragraph (h) of proposed § 335.4.

Paragraph (i) of proposed § 335.4 would require the person to whom a permit for the introduction of a regulated organism has been issued to maintain records for 10 years that identify the regulated organism as specifically as it can be determined, identify the characteristics of the regulated organism, and state the disposition of the regulated organism. Proposed paragraph (i) provides that an APHIS inspector shall be allowed access to records required to be maintained under the proposed paragraph for inspection and copying during normal business hours. The proposed requirement that the records be kept for 10 years following the issuance of a permit is based on APHIS' belief that most projects involving the introduction of a regulated organism would have been completed by that time, or that substantial information regarding the biology and potential effects on the environment of the regulated organism would have been obtained within 10 years. This information would provide APHIS with data regarding the nature of the organism that may have a bearing on APHIS' review of subsequent applications to introduce the same or similar organisms.

*Nonindigenous Organisms Exempted From Regulation Under This Part (§ 335.5)*

The taxa listed in § 335.2(a) include species that are known plant pests, which gives us reason to believe that other species within those taxa may be plant pests. However, some taxa may also include species that present no significant plant pest risk and could safely be introduced into the United States without restriction. Therefore, § 335.5 of the proposed regulations provides a process by which a person could request that a taxon of nonindigenous organism be exempted from regulation under proposed part 335.

Under proposed § 335.5(a), exemptions could be obtained for the introduction of a regulated organism

into the entire United States, the continental United States (the conterminous 48 States and Alaska), Hawaii, Puerto Rico, the Northern Mariana Islands, or an individual U.S. territory or possession, or a combination thereof.

Paragraph (b) of proposed § 335.5 sets forth the information that would have to be submitted to the Administrator with a person's request to have a regulated organism exempted from regulation:

- (1) The name, address, telephone number, and facsimile number of the person submitting the request;
- (2) The scientific name, common name, and any other information that serves to identify the regulated organism as specifically as possible (including the subspecies, race, and strain of the regulated organism) that the person believes should be exempted from regulation under this part and a description of the methods used to establish the identity of the regulated organism;
- (3) A description of the life cycle, biology, and ecology of the regulated organism;
- (4) Whether the regulated organism has been genetically modified (if so, include a description of the genetic modification);
- (5) The established range of the regulated organism in the United States;
- (6) Whether the regulated organism has been released into the environment in the area or areas of the United States for which the exemption is being requested and, if so, the location and date of the release;
- (7) A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment;
- (8) The effect of the regulated organism on the environment in its established range;
- (9) The host specificity of the regulated organism under both artificial and natural conditions;
- (10) References to any published and unpublished documents that support the information required by paragraphs (b)(1)(ii) through (b)(1)(ix) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application; and
- (11) A list of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms to which specimens of the regulated organism have been submitted, and the identification numbers assigned to the specimens.

Ten of these 11 data elements are similar to those found in paragraphs (b)

and (e) of proposed § 335.4, which contain the data elements that must be addressed in an application for a permit to release a regulated organism into the environment. The eleventh proposed element (a list of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms to which specimens of the regulated organism have been submitted, and the identification numbers assigned to the specimens) would provide a reference for APHIS and is also proposed as a permit condition for the release of a regulated organism into the environment in proposed § 335.6(c). These 11 data elements are intended to provide APHIS with information necessary to assess the environmental and plant pest risks associated with exempting a nonindigenous organism from regulation under proposed part 335.

Proposed § 335.5(b)(2) provides that after receiving a request for exemption, APHIS would conduct a review to determine whether the request for an exemption contained all the information required by proposed § 335.5(b)(1). This review would be completed within 30 days of APHIS' receipt of the request for an exemption. Upon completion of that review, we would inform the person requesting the exemption of the date the request was received, which would be the date that the review period had commenced (or, if the request was incomplete, what additional information was needed). Once the request for exemption is complete, APHIS would commence its review of the request. When the request contains all the information required by proposed § 335.5(b)(1), we believe that a 120-day review period—which is proposed in § 335.5(b)(2)—would be sufficient for APHIS to thoroughly examine all aspects of the request for an exemption.

If, based upon its review of the request, APHIS finds that exempting the regulated organism from regulation would not present a significant plant pest risk, APHIS would publish a notice of proposed rulemaking in the **Federal Register**, proposing to add the organism to the list of regulated organisms exempted from the regulations in proposed part 335. If the public comments do not contain any supportable information that indicate the organism should not be exempt from regulation under proposed part 335, a final rule adding the organism to the list of exempted nonindigenous organisms would be published in the **Federal Register**.



Conversely, if APHIS determines that the available information could not support a finding that exempting the regulated organism from regulation would not present a significant plant pest risk, the request would be denied. The person requesting the exemption would be informed of the denial in writing and given the opportunity to appeal. The appeal process would be set forth in proposed § 335.5(b). The denial of an exemption request would not preclude the person who had requested the exemption from applying for a permit for the introduction of the same regulated organism.

There may be occasions where APHIS determines, without having received a request from a member of the public, that a regulated organism could be exempted from regulation under this proposed part without presenting a significant plant pest risk. Therefore, proposed § 335.5(c) provides that in such cases, APHIS would publish a notice of proposed rulemaking in the **Federal Register**, proposing to add the organism to the list of exempted nonindigenous organisms in proposed § 335.5(d). If the public comment period did not produce any supportable information that indicated the organism

should not be exempted from regulation, a final rule adding the organism to the list of exempted nonindigenous organisms would be published in the **Federal Register**.

In this proposed rule, the list of exempted nonindigenous organisms in proposed § 335.5(d) consists of 13 types of organisms that APHIS believes should be exempted from regulation under proposed part 335. The exemption would apply to the introduction of these organisms into the entire United States. These organisms are:

Class	Order	Family	Scientific or common name
Arachnida .....	Scorpiones .....	.....	Scorpions.
Arachnida .....	Pseudoscorpiones .....	.....	Pseudoscorpions.
Arachnida .....	Solfugae .....	.....	Windscorpions.
Arachnida .....	Amblypygi .....	.....	Tailless whipscorpions.
Arachnida .....	Opiliones .....	.....	Daddy-longlegs/harvestmen.
Arachnida .....	Aranae .....	Theraphosidae .....	Tarantulas.
Insecta .....	Blattodea .....	.....	Cockroaches.
Insecta .....	Diptera .....	Culicidae .....	Mosquitoes.
Insecta .....	Diptera .....	Muscidae .....	<i>Musca domestica</i> .
Insecta .....	Diptera .....	Drosophilidae .....	<i>Drosophila melanogaster</i> .
Chilopoda .....	.....	.....	Centipedes.
Diploda .....	.....	.....	Millipedes.

A permit would not be required under proposed part 335 to introduce these organisms into the United States because, based on APHIS' experience issuing plant pest permits, we do not believe that the above types of organisms would need to be regulated under proposed part 335 in order to prevent the introduction of plant pests into the United States.

*Conditions for the Introduction of Regulated Organisms (§ 335.6)*

This section of the proposed regulations contains conditions that would apply to the introduction of regulated organisms. As mentioned above in the discussion of proposed § 335.4(g), any additional conditions that would apply specifically to the introduction of a particular regulated organism would be listed on the permit issued for that introduction. These proposed conditions are designed to prevent the introduction and dissemination of plant pests.

Paragraph (a) of proposed § 335.6 contains the conditions that would apply to the importation of regulated organisms. We would require regulated organisms imported into the United States to be accompanied by a permit and imported through a port of first arrival that has a plant inspection station. Given the nature of some regulated organisms, we believe it is necessary to route them through one of

APHIS' plant inspection stations, which have special inspection and treatment facilities. In order to reduce the risk of the spread of plant pests, and to help prevent a regulated organism's accidental release into the environment, we would further require that imported regulated organisms be moved from the port of first arrival only to the destination specified on the permit. We would also require the regulated organism to be enclosed in a container that meets the requirements of proposed § 335.8, and that the container remains unopened until the regulated organism arrives at the destination specified on the permit. The regulated organism could not be accompanied by an organism or article not specified on the permit.

To facilitate the handling of the regulated organism at the port of first arrival, we would require that the outside of the container bear a label issued by APHIS; the label would identify the container so that it would be handled by the APHIS inspector as quickly as possible. The outside of the container in which the regulated organism is moved would also have to accurately identify the regulated organism, the person to whom the permit was issued, the destination of the regulated organism, the return address of the sender of the regulated organism, and the number of the permit authorizing the importation. By having

this information accompanying the regulated organism at the time of its arrival at the port of first arrival, we could avoid unnecessary delays that might result from inadequate identification of the container's contents.

We would require the permittee to agree to notify the Administrator immediately if there is an accidental or unauthorized release of the regulated organism into the environment, or within 5 days if there are any characteristics of the regulated organism that are substantially different from those listed in the application for a permit.

In certain cases, APHIS may determine that a regulated organism must be destroyed, disposed of, or subjected to other remedial measures to prevent the spread of plant pests. Therefore, in situations where the regulated organism presents a risk of disseminating plant pests, the permittee would be required to present the regulated organism to the Administrator for disposition.

Paragraph (b) of proposed § 335.6 contains the proposed conditions that would apply to the interstate movement of regulated organisms. Regulated organisms moved interstate would have to meet, with two exceptions, the same conditions as imported regulated organisms under this section of the proposed regulations. Regulated

organisms moved interstate would have to be accompanied by a permit, moved only to the destination specified on the permit, moved in a container that meets the requirements of proposed § 335.8, and moved without any other organism or article, except as specified on the permit. Further, the container in which the regulated organisms are moved would have to remain unopened until its arrival at the destination specified on the permit. The outside of the container would have to accurately identify the regulated organism, the person to whom the permit was issued, the destination of the regulated organism, the return address of the sender of the regulated organism, and the number of the permit authorizing the interstate movement. The permittee would also have to agree to notify the Administrator immediately if there is an accidental or unauthorized release of the regulated organism into the environment, or within 5 days if there are any characteristics of the regulated organism that are substantially different from those listed in the application for a permit. In situations where the regulated organism presented a risk of disseminating plant pests, the permittee would be required to present the regulated organism to the Administrator for disposition.

For regulated organisms released into the environment, any specific conditions would be determined by the nature of the individual release. Therefore, the only conditions that would apply to the release of all regulated organism into the environment would be: (1) That the release be authorized by a permit and conducted in accordance with the conditions of the permit; (2) that the permittee notify APHIS immediately if there were an accidental or unauthorized release of the regulated organism into the environment, or within 5 days if there were any characteristics of the regulated organism that were substantially different from those listed in the application for a permit; (3) that, in situations where the regulated organism presented a risk of disseminating plant pests, the permittee would present the regulated organism to the Administrator for disposition; and (4) that specimens of the regulated organism be submitted to the collections of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms. The identification numbers assigned to the specimens would have to have been provided to APHIS prior to the release to provide a reference for APHIS.

#### *Facilities for the Containment of Regulated Organisms (§ 335.7)*

This section of the proposed regulations contains the requirements that would apply to a facility into which a regulated organism would be imported or moved interstate. Under the proposed regulations, the Administrator would approve the use of a facility for the containment of a regulated organism only if the facility met the requirements of proposed § 335.7.

We would require that the facility be constructed and operated in a manner that would prevent the escape and dissemination of the regulated organism. To that end, we would require that the facility's physical structure possess adequate water, air, and waste handling systems, as well as adequate entryways, windows, and facility structure to contain the regulated organism and prevent the unauthorized entry of organisms and people. In terms of its operation, we would require that the facility have procedural safeguards and be operated in a manner that would prevent the escape of a regulated organism and would prevent the unauthorized entry of organisms and people.

We would require that the facility have a means of inactivating or sterilizing the regulated organism and any host material, containers, or other material used for the regulated organism. We believe this requirement is necessary to ensure that, for example, unauthorized material accompanying a regulated organism could be destroyed if it constituted a plant pest risk. Additionally, there may be circumstances under which the Administrator determines that the destruction or disposal of a regulated organism is necessary to prevent the spread of a plant pest.

Because there may be cases in which the circumstances of a particular introduction dictate the need for additional safeguards, we would further require that the facility and its operation meet any other conditions the Administrator deemed necessary to prevent the escape of a regulated organism and prevent the unauthorized entry of organisms and people.

Finally, we would require that the operator of the facility maintain certain records regarding the regulated organism during the time the organism is held in the facility. The records would have to identify the regulated organism, the person from whom the regulated organism was received, the date the regulated organism was received at the facility, and the disposition of the regulated organism.

Those records would be necessary for APHIS to determine whether a regulated organism has been moved and held in accordance with the conditions of the permit authorizing its introduction. Therefore, we propose to require that an APHIS inspector be allowed to inspect and copy those records during normal business hours.

#### *Container Requirements for the Movement of Regulated Organism (§ 335.8)*

Proposed § 335.8 specifies the container requirements for the importation and interstate movement of a regulated organism and any material moved with the regulated organism. A regulated organism must be properly packaged to maximize its chances of survival and minimize the possibility of an accidental release into the environment during movement. For those reasons, we would prohibit the importation and interstate movement of any regulated organism unless the regulated organism is enclosed in a container that meets the requirements of this section.

For the purposes of this section, a regulated organism and any material moved with a regulated organism would be divided into five categories: plants and plant parts, seeds, microorganisms, arthropods, and other organisms. Each category is designed to provide safeguards commensurate with the level of risk that would be presented by the importation or interstate movement of an organism in that category.

Under proposed § 335.8(b)(1), all plants or plant parts, except seeds and cells, would have to be enclosed in a sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container, and then enclosed in a sturdy, sealed, outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength. Under proposed § 335.8(b)(2), all seeds would have to be enclosed in a sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container. The sealed plastic bag or equivalent leakproof container would have to be enclosed within a second sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container. Each plastic bag or equivalent leakproof container would have to be independently capable of preventing the seeds from escaping the container. Each set of containers would have to be enclosed in a sturdy outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

All microorganisms, such as fungi, bacteria, nematodes, or cells, would have to be enclosed in a container as specified in paragraph (b)(3)(i) or (b)(3)(ii) of proposed § 335.8.

Microorganisms not exceeding 50 mL in volume would have to be enclosed in a durable, watertight primary container, which would have to be enclosed in a second durable, watertight container (secondary container). Several primary containers could be enclosed in a single secondary container if the total volume of all the primary containers enclosed in a single secondary container did not exceed 50 mL. The space at the top, bottom, and sides between the primary and secondary containers would have to contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s). The secondary container would then have to be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

Microorganisms that exceeded a volume of 50 mL would have to comply with the requirements described in the above paragraph. In addition, a shock-absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, would have to be placed at the top, bottom, and sides between the secondary container and the outer container. Single primary containers could not contain more than 1,000 mL of material. However, two or more primary containers whose combined volumes do not exceed 1,000 mL could be enclosed in a single secondary container. The maximum amount of microorganisms that could be enclosed within a single outer container could not exceed 4,000 mL.

If dry ice was used as a refrigerant, it would have to be placed between the secondary container and the outer container. The shock-absorbing material would have to be placed so that the secondary container would not become loose inside the outer container as the dry ice sublimates.

Insects, mites, or other arthropods would have to be enclosed in a container as specified for arthropods in paragraph (b)(4) of proposed § 335.8 or in a container specified for microorganisms described in paragraph (b)(3) of proposed § 335.8. Under proposed § 335.8(b)(4), arthropods (any life stage) would have to be enclosed in a primary container (insulated vacuum container, metal, or plastic) and the container would have to be sealed to prevent escape of the arthropods. The primary container would have to be

enclosed in a secondary container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs could also be enclosed in the secondary container; and sufficient packing material would have to be added around the primary container to prevent movement of the primary container within the secondary container. The secondary container would have to be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

Any organism not covered in paragraph (b)(1), (b)(2), or (b)(4) of proposed § 335.8 that did not require continuous access to atmospheric oxygen would have to be enclosed in a container as specified in paragraph (b)(3) or (b)(4) of this section. Any organism that was not a plant and that required continuous access to atmospheric oxygen would have to be enclosed in a primary container constructed with a sturdy, crush-proof frame of wood, metal, or other material of equivalent strength, surrounded by mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the container, with the edges and seams of the mesh or netting sealed to prevent the escape of organisms. Each primary container would have to be enclosed in a larger secondary container constructed of wood, metal, or other material of equivalent strength. The primary and secondary containers would have to be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container could have air holes or spaces in the sides and/or ends of the container, provided that the outer container would have to retain sufficient strength to prevent crushing of the primary and secondary containers.

We believe that these proposed requirements would be sufficient to prevent the accidental release of the regulated organism and any material moved with the organism.

We understand that there may be unique circumstances, such as the nature, volume, or life stage of a regulated organism, that could make these proposed container requirements inappropriate for the importation of interstate movement of a particular regulated organism. For that reason, we would allow a person to request a variance from the container requirements by submitting a written statement to APHIS describing why the applicable container requirements are inappropriate for the regulated organism

that the person proposes to move, and what container requirements the person would use in lieu of the applicable container requirements. APHIS would make a decision regarding the variance request and would inform the applicant of the decision prior to the issuance of a permit. If APHIS granted the variance request, a permit would be issued if APHIS had determined from its review of the permit application that the regulated organism could be introduced without risk of plant pest dissemination. If APHIS denied the variance request, the applicant could submit an appeal to the Administrator by following the procedure detailed in the proposed regulations; however, no permit would be issued until such time as the appeal was resolved and the applicant agreed to abide by APHIS' decision.

#### *Costs and Charges (§ 335.9)*

Proposed § 335.9 relates to costs and charges that would apply in connection with the services of an APHIS inspector. It is the policy of APHIS that the services of an APHIS inspector during regularly assigned hours of duty and at the usual places of duty be furnished without cost to persons requiring inspection, unless a user fee is payable under 7 CFR part 354. There are, however, no user fees currently in place that would affect the permitting or inspection activities that would be carried out under the proposed regulations.

Proposed § 335.9 further provides that any costs or charges incidental to inspection or to compliance with the provisions of this part, other than an APHIS inspector's services, are not the responsibility of the USDA.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been determined to be significant and was reviewed by the Office of Management and Budget under Executive Order 12866.

We are proposing to establish comprehensive regulations governing the introduction (importation, interstate movement, and release into the environment) of certain regulated organisms. The proposed regulations would clarify the permit application process and provide a means of screening regulated organisms prior to their introduction to determine the potential plant pest risk associated with a particular introduction. According to the OTA report cited above, harmful nonindigenous species have caused an economic loss of approximately \$97 billion between 1906 and 1991. When weighed against that figure, the costs of

implementing or complying with these proposed regulations are insignificant.

The proposed regulations clearly set out the information that APHIS would require to be able to make a decision concerning the plant pest risk associated with a regulated organism, so prospective applicants would not find themselves wasting scarce resources seeking clarification or interpretation of the existing plant pest regulations. These improvements are expected to encourage and facilitate research in the area of nonindigenous organisms.

In 1992, APHIS issued 3,375 permits under 7 CFR part 330 for the importation, interstate movement, or release into the environment of organisms, nearly 3 times the 1982 total of 1,167 permits issued. The average total cost (using the 1992 data) to APHIS to process an application was approximately \$139. No user fees have been charged to the applicants.

Under the current system, the processing of an application can be a lengthy process. It takes, on average, approximately 5 to 30 days to issue a permit for importation or interstate movement of an organism, while it may take as long as a year to process an application for the release of an organism into the environment. This time variability is partly a function of the level of risk assessment required, but the adequacy of the initial information provided by the applicant plays an important role. We anticipate that the permit application process set forth in the proposed regulations would speed up the permit application review process by ensuring that sufficient data are provided by applicants from the start of APHIS' review of the application.

The applicants for permits to introduce nonindigenous organisms have been researchers, scientists, private businesses, and agricultural producers. Approximately two-thirds of all applicants have been nonprofit entities. Most of the applicants are considered to be small entities. Of the three types of permits that would be issued under these proposed regulations—importation, interstate movement, and release into the environment—we believe that an application for a permit to release a regulated organism into the environment would take the longest to prepare. We estimate that a Ph.D. researcher working with clerical support for approximately 2 weeks to prepare an application for a permit to release a regulated organism into the environment would cost, based on their estimated salaries, less than \$5,000. We anticipate that the costs of preparing a permit application for the majority of

the regulated organisms covered by the proposed regulations would not be significant because most, if not all, of the data that would be required would already be known to the applicant, thus minimizing the amount of time spent preparing a permit application.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### **Executive Order 12778**

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### **National Environmental Policy Act**

APHIS has determined that the preparation of an environmental assessment was not necessary for the proposed regulations. The proposed regulations are procedural in nature and would not irrevocably commit APHIS to any decision concerning the issuance of any permit for the release into the environment of a regulated organism. As a procedural regulation, the proposed rule would advise persons of what data to submit in a permit application so that APHIS would be able to decide whether a permit could be granted. For an application for a permit to release a regulated organism into the environment, the required data would be used to prepare an environmental assessment as part of APHIS' decision-making process. APHIS would retain the authority to grant, deny, or revoke a permit on a case-by-case basis.

#### **Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to the Office of Management and Budget. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention:

Desk Officer for APHIS, Washington, DC 20503. Please send a copy of your comments to: (1) Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, P.O. Drawer 810, Riverdale, MD 20738, and (2) Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250.

#### **List of Subjects in 7 CFR Part 335**

Imports, Packaging and containers, Plant diseases and pests, Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 335 would be added to read as follows:

#### **PART 335—INTRODUCTION OF NONINDIGENOUS ORGANISMS**

Sec.

- 335.1 Definitions.
- 335.2 Regulated organisms.
- 335.3 General restrictions on the introduction of regulated organisms.
- 335.4 Permits for the introduction of regulated organisms.
- 335.5 Nonindigenous organisms exempted from regulation under this part.
- 335.6 Conditions for the introduction of regulated organisms.
- 335.7 Facilities for the containment of regulated organisms.
- 335.8 Container requirements for the movement of regulated organisms.
- 335.9 Costs and charges.

**Authority:** 7 U.S.C. 150aa-150jj, 151-164a, 167, and 1622(n); 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.17, 2.51, and 371.2(c).

#### **§ 335.1 Definitions.**

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other individual to whom the Administrator delegates authority to act in his or her stead.

**Animal and Plant Health Inspection Service (APHIS).** The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

**APHIS inspector.** Any employee of the Animal and Plant Health Inspection Service or any other individual authorized by the Administrator to enforce this part.

**Environment.** All land, air, and water; and all living organisms in association with land, air, and water.

**Established.** The condition of a species that has formed a self-sustaining, free-living population at a given location.

*Established range.* The area in which a species maintains a self-sustaining, free-living population.

*Import.* To bring into the territorial limits of the United States.

*Interstate.* From any State into or through any other State, or within the District of Columbia, American Samoa, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Introduce (introduction).* To move or to attempt to move into or through the United States, to release or attempt to release into the environment, or to move or attempt to move interstate.

*Move (moving, movement).* To ship, offer for shipment, enter, offer for entry, import, offer for importation, receive for transportation, carry, mail, or otherwise transport or allow to be transported into, through, or within the United States.

*Nonindigenous organism.* Any organism proposed for introduction into any area of the United States beyond its established range.

*Permit.* An authorization issued by the Administrator for the introduction of a regulated organism.

*Person.* Any individual, partnership, corporation, company, society, association, or other legal entity or organized group.

*Plant.* Any stage of any member of the plant kingdom including, but not limited to, trees, plant tissue cultures, plantlet cultures, pollen, shrubs, vines, cuttings, grafts, scions, buds, roots, seeds, cells, tubers, and stems.

*Plant pest.* Any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts of parasitic plants, viruses, or any organisms similar to or allied with any of the organisms previously identified in this definition, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or plant parts, or any processed, manufactured, or other products of plants.

*Plant product.* Any processed or manufactured plant or plant part.

*Port of first arrival.* The land area (such as a seaport, airport, or land border station) where a person, or a land, water, or air vehicle, first arrives after entering the United States, and where inspection of articles is carried out by APHIS inspectors.

*Regulated organism.* Any living stage of any nonindigenous organism belonging to the taxa listed in § 335.2(a) that is not listed in § 335.2(b) or exempt in accordance with § 335.5.

*Release into the environment.* The use of a regulated organism outside the constraints of physical confinement.

*State.* Any State, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other territory or possession of the United States.

*United States.* All of the States.

### § 335.2 Regulated organisms.

(a) The taxonomic groups listed in paragraph (a)(1) of this section include organisms that are known plant pests. Therefore, there is reason to believe that other organisms within the taxonomic groups listed in paragraph (a)(1) of this section may be or may contain plant pests and, except for those organisms listed in paragraph (b) of this section or exempt in accordance with § 335.5, are regulated organisms. Within any taxonomic group included on the list in this paragraph, the lowest unit of classification listed is the taxonomic group that may contain regulated organisms. Organisms belonging to all lower taxa contained within the groups listed in this paragraph are included as organisms that may be or may contain plant pests.

#### (1) Group:

Viroids  
Superkingdom Prokaryotae  
Kingdom Virus

All members of groups containing plant viruses, and all other plant and insect viruses.

Kingdom Monera

Division Bacteria

Family Pseudomonadaceae

Genus Pseudomonas  
Genus Xanthomonas

Family Rhizobiaceae

Genus Rhizobium  
Genus Bradyrhizobium  
Genus Agrobacterium  
Genus Phyllobacterium

Family Enterobacteriaceae

Genus Erwinia

Family Streptomycetaceae

Genus Streptomyces

Family Actinomycetaceae

Genus Actinomyces

Coryneform group

Genus Clavibacter  
Genus Arthrobacter  
Genus Curtobacterium  
Genus Corynebacteria

Gram-negative phloem-limited bacteria associated with plant diseases.

Gram-negative xylem-limited bacteria associated with plant diseases.

And all other bacteria associated with plant or insect diseases.

Rickettsiaceae

Rickettsial-like organisms associated with insect diseases.

Class Mollicutes

Order Mycoplasmatales

Family Spiroplasmataceae

Genus Spiroplasma

Mycoplasma-like organisms associated with plant diseases.

Mycoplasma-like organisms associated with insect diseases.

Superkingdom Eukaryotae

Kingdom Plantae

Subkingdom Thallobionta

Division Chlorophyta

Genus Cephaleuros  
Genus Rhodochytrium  
Genus Phyllosiphon

Division Myxomycota

Class Plasmodiophoromycetes

Division Eumycota

Class Chytridiomycetes

Order Chytridiales

Class Oomycetes

Order Lagenidiales

Family Lagenidiaceae

Family Olpidiopsidaceae

Order Peronosporales

Family Albuginaceae

Family Peronosporaceae

Family Pythiaceae

Order Saprolegniales

Family Saprolegniaceae

Family Leptolegnillaceae

Class Zygomycetes

Order Mucorales

Family Choanephoraceae

Family Mucoraceae

Family Entomophthoraceae

Class Hemiascomycetes

Family Protomycetaceae

Family Taphrinaceae

Class Loculoascomycetes

Order Myriangiales

Family Elsinoeaceae

Family Myriangiaceae

Order Asterinales

Order Dothideales

Order Chaetothyriales

Order Hysteriales

Family Parmulariaceae

Family Phillipsiellaceae

Family Hysteriaceae

Order Pleosporales

Order Melanommatales

Class Plectomycetes

Order Eurotiales

Family Ophiostomataceae

Order Ascophaerales

Class Pyrenomycetes

Order Erysiphales

Order Meliolales

Order Xylariales	Genus <i>Harveya</i>	Suborder Mesostigmata
Order Diaporthales	Genus <i>Hyobanche</i>	Superfamily Ascoidea
Order Hypocreales	Genus <i>Lathraea</i>	Superfamily Dermanssoidea
Order Clavicipitales	Genus <i>Melampyrum</i>	Order Acariformes
Class Discomycetes	Genus <i>Melasma</i>	Suborder Prostigmata
Order Phacidiales	Genus <i>Orthantha</i>	Superfamily Eriophyoidea
Order Helotiales	Genus <i>Orthocarpus</i>	Superfamily Tetranychoidae
Family Ascocorticaceae	Genus <i>Pedicularis</i>	Superfamily Eupodoidea
Family Hemiphacidiaceae	Genus <i>Rhamphicarpa</i>	Superfamily Tydeoidea
Family Dermataceae	Genus <i>Rhinanthus</i>	Superfamily Erythraenoidea
Family Sclerotiniaceae	Genus <i>Schwalbea</i>	Superfamily Trombidioidea
Order Cytrariales	Genus <i>Seymeria</i>	Superfamily Hydryphantoidea
Order Medeolariales	Genus <i>Siphonostegia</i>	Superfamily Tarsonemoidea
Order Pezziales	Genus <i>Sopubia</i>	Superfamily Pyemotoidea
Family Sarcosomataceae	Genus <i>Tozzia</i>	Suborder Astigmata
Family Sarcoscyphaceae	Family Viscaceae—parasitic species	Superfamily Hemisarcoptoidea
Class Teliomycetes	Kingdom Animalia	Superfamily Acaroidea
Class Phragmobasidiomycetes	Subkingdom Protozoa	Class Diplopoda
Family Auriculariaceae	Genus <i>Phytomonas</i>	Order Polydesmida
Family Ceratobasidiaceae	And all Protozoa associated with insect diseases.	Class Insecta
Class Hymenomycetes	Subkingdom Eumetazoa	Order Collembola
Order Exobasidiales	Phylum Nemata	Family Sminthoridae
Order Agaricales	Class Secernentea	Order Isoptera
Family Corticiaceae	Order Tylenchida	Order Thysanoptera
Family Hymenochaetaceae	Family Anguinidae	Order Orthoptera
Family Echinodontiaceae	Family Belonolaimidae	Family Acrididae
Family Fistulinaceae	Family Caloosiidae	Family Gryllidae
Family Clavariaceae	Family Criconematidae	Family Gryllacrididae
Family Polyporaceae	Family Dolichodoridae	Family Gryllotalpidae
Family Tricholomataceae	Family Fergusobiidae	Family Phasmatidae
Class Hyphomycetes	Family Hemicycliophoridae	Family Ronaleidae
Class Coelomycetes	Family Heteroderidae	Family Tettigoniidae
And all other fungi associated with plant or insect diseases.	Family Hoplolaimidae	Family Tetrigidae
Subkingdom Embryobionta	Family Meloidogynidae	Order Hemiptera
Division Magnoliophyta	Family Nacobbidae	Family Thaumastocoridae
Family Balanophoraceae—parasitic species	Family Neotylenchidae	Family Aradidae
Family Cuscutaceae—parasitic species	Family Nothotylenchidae	Superfamily Piesmatoidea
Family Hydnoraceae—parasitic species	Family Paratylenchidae	Superfamily Lygaeoidea
Family Krameriaceae—parasitic species	Family Pratylenchidae	Superfamily Idiostoloidea
Family Lauraceae—parasitic species	Family Tylenchidae	Superfamily Coreoidea
Genus <i>Cassytha</i>	Family Tylenchulidae	Superfamily Pentatomoidea
Family Lennoaceae—parasitic species	Order Aphelenchida	Superfamily Pyrrhocoroidea
Family Loranthaceae—parasitic species	Family Aphelenchoididae	Superfamily Tingoidea
Family Myzodendraceae—parasitic species	Class Adenophorea	Superfamily Miroidea
Family Olacaceae—parasitic species	Order Dorylaimida	Order Homoptera
Family Orobanchaceae—parasitic species	Family Longidoridae	Order Coleoptera
Family Rafflesiaceae—parasitic species	Family Trichodoridae	Family Anobiidae
Family Santalaceae—parasitic species	Phylum Mollusca	Family Apionidae
Family Scrophulariaceae—parasitic species	Class Gastropoda	Family Anthribidae
Genus <i>Bartsia</i>	Subclass Pulmonata	Family Bostrichidae
Genus <i>Buchnera</i>	Order Basommatophora	Family Brentidae
Genus <i>Buttonia</i>	Superfamily Planorbacea	Family Bruchidae
Genus <i>Castilleja</i>	Order Stylommatophora	Family Buprestidae
Genus <i>Centranthera</i>	Subfamily Strophocheilacea	Family Byturidae
Genus <i>Cordylanthus</i>	Family Succineidae	Family Cantharidae
Genus <i>Dasistoma</i>	Superfamily Achatinaceae	Family Carabidae
Genus <i>Euphrasia</i>	Superfamily Arionaceae	Family Cerambycidae
Genus <i>Gerardia</i>	Superfamily Limacacea	Family Chrysomelidae
	Superfamily Helicacea	Family Coccinellidae
	Order Systellommatophora	Subfamily Epilachninae
	Superfamily Veronicellacea	Family Curculionidae
	Phylum Arthropoda	Family Dermestidae
	Class Arachnida	Family Elateridae
	Order Parasitiformes	Family Hydrophilidae
		Genus <i>Helophorus</i>
		Family Lyctidae
		Family Meloidae

Family Mordellidae  
 Family Platypodidae  
 Family Scarabaeidae  
   Subfamily Melolonthinae  
   Subfamily Rutelinae  
   Subfamily Cetoniinae  
   Subfamily Dynastinae  
 Family Scolytidae  
 Family Selbytidae  
 Family Tenebrionidae  
 Order Lepidoptera  
 Order Diptera  
 Family Agromyzidae  
 Family Anthomyiidae  
 Family Cecidomyiidae  
 Family Chloropidae  
 Family Ephydriidae  
 Family Lonchaeidae  
 Family Muscidae  
   Genus Atherigona  
 Family Otitidae  
   Genus Euxeta  
 Family Syrphidae  
 Family Tephritidae  
 Family Tipulidae  
 Order Hymenoptera  
 Family Apidae  
 Family Aphelinidae  
 Family Braconidae  
   Genus Perilitus  
 Family Caphidae  
 Family Chalcidae  
 Family Cynipidae  
 Family Diapriidae  
   Genus Ismarus  
 Family Encyrtidae  
 Family Eulophidae  
 Family Eurytomidae  
 Family Formicidae  
 Family Ichneumonidae  
   Subfamily Cryptinae  
   Subfamily Diplazontinae  
   Subfamily Gelinae  
   Subfamily Mesochorinae  
   Subfamily Ephialtinae  
 Family Psilidae  
 Family Pteromalidae  
 Family Scelionidae  
   Genus Gryon  
   Genus Scelio  
 Family Signiphoridae  
 Family Siricidae  
 Family Tenthredinidae  
 Family Torymidae  
 Family Trichogrammatidae  
 Family Xylocopidae

(2) Unclassified organisms and organisms whose classification is unknown.

(b) An organism from a taxonomic group listed in paragraph (a) of this section is not a regulated organism under this part if the introduction of that organism is regulated under any of the following regulations:

(1) Live bees other than honeybees of the genus *Apis* regulated under § 319.76 of this chapter;

(2) Plant pests regulated under § 330.200 of this chapter;

(3) Live honeybees of the genus *Apis* regulated under part 322 of this chapter;

(4) Organisms genetically engineered through recombinant DNA techniques regulated under part 340 of this chapter;

(5) Noxious weeds regulated under part 360 of this chapter;

(6) Organisms and vectors that may introduce or disseminate contagious animal diseases regulated under 9 CFR part 122; and

(7) Etiologic microorganisms that cause disease in humans (including bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, arthropods, parasites, and the hosts and vectors that may carry these etiological microorganisms) that are regulated under 42 CFR part 71, unless the microorganism, host, or vector could also be a plant pest.

#### § 335.3 General restrictions on the introduction of regulated organisms.

(a) No person shall introduce any regulated organism unless the introduction is authorized by a permit issued in accordance with § 335.4 and is in conformity with this part.

(b) Any regulated organism that is introduced not in compliance with this part shall be subject to destruction, disposal, or the remedial measures that the Administrator determines are necessary to prevent the dissemination into the United States, or dissemination within the United States, of plant pests.

#### § 335.4 Permits for the introduction of regulated organisms.

(a) *Permit applications.* An application for a permit to introduce a regulated organism shall be submitted to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support, 4700 River Road Unit 133, Riverdale, MD 20737-1236. The application shall state the type of permit being sought by the applicant (import permit, interstate movement permit, or permit for release into the environment).

(1) A person may apply for a permit for the importation or interstate movement of regulated organisms within a taxon of a higher level than species (genus, family, order, class, phylum) in lieu of submitting an application for the importation or interstate movement of each species of regulated organism. A permit issued for the importation or interstate movement of regulated organisms within a taxon of a higher level than species will be valid only for the importation or interstate movement of those regulated organisms

imported or moved interstate between those locations specified on the permit. If a person seeks to import or move interstate a regulated organism not specified on the permit, or to import or move interstate a regulated organism from or to a location not listed on the permit, a new application must be submitted to the Administrator.

(2) If an application contains any information deemed to be trade secret or confidential business information (CBI), each page of the application must be marked "CBI Copy" and those portions of the application that are deemed CBI must be so designated. In addition, a second copy of the application shall be submitted that has all such CBI deleted and is marked "CBI Deleted" on each page of the application where CBI was deleted.

(3) An application for a permit for the importation or interstate movement of a regulated organism must be received by the Administrator at least 30 days prior to each importation or interstate movement. An application for a permit for the release into the environment of a regulated organism must be received by the Administrator at least 120 days prior to the release into the environment.

(4) The Animal and Plant Health Inspection Service (APHIS), within 15 days of the receipt of an application for a permit for the importation or interstate movement of a regulated organism and within 30 days of the receipt of an application for a permit for the release into the environment of a regulated organism, will review the application for a permit to determine whether the application contains all of the information required by this section. If the application contains all of the information required by this section, APHIS will notify the person applying for a permit of the date that the application was received, which will be the commencement date of a 30-day review period for applications for importation or interstate movement or a 120-day review period for applications for release into the environment. If the application does not contain all of the information required by this section, APHIS will advise the person applying for a permit of the additional information that must be received by the Administrator to complete the application for a permit. APHIS will commence the applicable review period upon receipt of the additional information, if, with the addition of that information, the application contains all of the information required by the section. When APHIS determines that an application contains all the information required by this section,

APHIS will submit a copy of the application marked "CBI Deleted" or "No CBI" to the State department of agriculture of the State where the introduction of the regulated organism is planned for the State's review and comment.

(5) Statutory or regulatory mandates may require that APHIS consult with other Federal agencies during its review of an application to release a regulated organism into the environment. In such cases, APHIS will notify the applicant, in writing, that APHIS is required to consult with other Federal agencies and that the consultation may result in the review period extending beyond the 120 days provided for in paragraph (a)(4) of this section.

(b) *Data requirements for all permit applications.* All applications for permits to introduce a regulated organism shall contain the following information:

(1) The name, address, telephone number, and facsimile number of the person applying for the permit;

(2) The scientific name, common name, and any other information that serves to identify the regulated organism as specifically as possible (including the subspecies, race, and strain of the regulated organism) and a description of the methods used to establish the identity of the regulated organism;

(3) A description of the measures that have been taken to establish that the regulated organism and any material associated with the introduction of the regulated organism do not contain any organisms not identified in the permit application;

(4) The intended use of the regulated organism;

(5) A description of the life cycle, biology, and ecology of the regulated organism;

(6) Whether the regulated organism has been genetically modified (if so, include a description of the genetic modification);

(7) The country and locality where the regulated organism was originally collected from nature, and the countries and localities where the regulated organism has been propagated and maintained since its collection;

(8) The established range of the regulated organism in the United States;

(9) The number of specimens or units of the regulated organism to be introduced;

(10) A description of any host material, substrate, medium, or organism that will accompany the regulated organism;

(11) If the application is for a permit to import a regulated organism, the

additional information required by paragraph (c) of this section;

(12) If the application is for a permit to move a regulated organism interstate, the additional information required by paragraph (d) of this section; and

(13) If the application is for a permit to release a regulated organism into the environment, the additional information required by paragraph (e) of this section.

(c) *Import permits.* In addition to the information required by paragraph (b) of this section, an application for a permit to import a regulated organism shall contain the following information:

(1) The country and locality from which the regulated organism will be exported to the United States;

(2) The address, telephone number, and facsimile number of the person in the exporting country from whom the regulated organism will be received;

(3) The port of first arrival in the United States through which the regulated organism is intended to be imported;

(4) The address (including the county), telephone number, and facsimile number of the facility to which the regulated organism will be delivered;

(5) A detailed description of the procedures, processes, and safeguards that will be used in the destination facility to prevent the escape and dissemination of the regulated organism and any material accompanying the regulated organism;

(6) The means by which the regulated organism will be imported into the United States (air mail, air freight, baggage, or motor vehicle); and

(7) The planned date(s) of the importation of the regulated organism.

(d) *Interstate movement permits.* In addition to the information required by paragraph (b) of this section, an application for a permit for the interstate movement of a regulated organism shall contain the following information:

(1) The State and locality from which the regulated organism will be moved interstate;

(2) The address, telephone number, and facsimile number of the person in the originating State from whom the regulated organism will be received;

(3) The address (including the county), telephone number, and facsimile number of the facility to which the regulated organism will be moved;

(4) A detailed description of the procedures, processes, and safeguards that will be used at the destination facility to prevent the escape and dissemination of the regulated organism

and any material accompanying the regulated organism;

(5) The means by which the regulated organism will be moved interstate (air mail, air freight, baggage, or motor vehicle); and

(6) The planned date(s) of the interstate movement of the regulated organism.

(e) *Release permits.* In addition to the information required by paragraph (b) of this section, an application for a permit to release a regulated organism into the environment shall contain the following information:

(1) The purpose of the release into the environment of the regulated organism;

(2) The anticipated date(s) of the release into the environment of the regulated organism;

(3) A description, including methods of release and release site(s), of the intended release into the environment of the regulated organism;

(4) A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment;

(5) The effect of the regulated organism on the environment in its established range;

(6) The host specificity of the regulated organism under both artificial and natural conditions; and

(7) References to any published and unpublished documents that support the information required by paragraphs (e)(4), (e)(5), and (e)(6) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application.

(f) *Facility and release site inspection.* The Administrator may inspect the facility into which a regulated organism proposed for importation or interstate movement is intended to be moved to determine whether the facility will meet the requirements of § 335.7. The Administrator may also inspect the site where a regulated organism is proposed to be released into the environment to assess the conditions described in the permit application.

(g) *Administrative action on applications.* After APHIS has reviewed an application which contains all the information required by this section, a permit for the introduction of the regulated organism will be issued or denied.

(1) If a permit is issued, the permit will specify the applicable conditions under this part for the introduction of the regulated organism. Each permit issued will be numbered and, unless revoked pursuant to paragraph (h) of this section, will be valid from the date of issuance until the expiration date specified on the permit. The expiration



date specified on the permit will be no more than 10 years from the date of issuance of the permit.

(2) If a permit is denied, the applicant will be promptly informed, in writing, of the reasons the permit was denied and given the opportunity to appeal the denial in accordance with paragraph (h) of this section. A permit application will be denied if:

(i) The applicant has had a permit revoked under paragraph (h) of this section during the 12 months prior to APHIS' receipt of the completed permit application, unless the revoked permit has been reinstated upon appeal.

(ii) An APHIS inspector is not allowed to inspect the facility into which a regulated organism proposed for importation or interstate movement is to be moved, or the site where a regulated organism is proposed to be released into the environment.

(iii) The Administrator determines, based on a review of the available information, that the introduction of the regulated organism would present a significant risk of plant pest dissemination and no adequate safeguards could be arranged to mitigate that risk.

(h) *Denial or revocation of permit; appeals.* Any permit that has been issued may be revoked, in writing, by an APHIS inspector or the Administrator if the APHIS inspector or the Administrator determines that the person to whom the permit was issued, or his or her agents or employees, has not complied with any condition specified on the permit or has violated any requirement of this part. Any person whose permit has been revoked or any person who has been denied a permit may appeal the decision in writing to the Administrator within 10 days after receiving the written notification of the revocation or denial. The appeal must state all of the facts and reasons upon which the person relies to show that the permit was wrongfully revoked or denied. The Administrator will grant or deny the appeal as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact and the person whose permit application was denied or permit was revoked requests a hearing, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(i) *Recordkeeping.* If a permit is issued for the introduction of a regulated organism, the person to whom the permit is issued must maintain records for 10 years that identify the regulated organism (as specifically as can be

determined), identify the characteristics of the regulated organism, and state the disposition of the regulated organism. An APHIS inspector shall, during normal business hours, be allowed to inspect and copy the records required to be maintained in accordance with this paragraph.

**§ 335.5 Nonindigenous organisms exempted from regulation under this part.**

(a) In accordance with the procedures set forth in paragraphs (b) and (c) of this section, a regulated organism may be exempted from regulation under this part. A nonindigenous organism exempted from regulation under this part may be introduced without restriction under this part into one or more of the areas listed in this paragraph:

- (1) The entire United States;
- (2) The continental United States (the conterminous 48 States and Alaska);
- (3) Hawaii;
- (4) Puerto Rico;
- (5) The Northern Mariana Islands; or
- (6) Any other U.S. territory or possession.

(b) *Requests for exemption.* (1) Any person who believes that a regulated organism should be exempted from regulation under this part shall submit a written request to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support, 4700 River Road Unit 133, Riverdale, MD 20737-1236. The request for an exemption from regulation under this part must include:

- (i) The name, address, telephone number, and facsimile number of the person submitting the request for the exemption;
- (ii) The scientific name, common name, and any other information that serves to identify the regulated organism as specifically as possible (including the subspecies, race, and strain of the regulated organism) that the person believes should be exempted from regulation under this part and a description of the methods used to establish the identity of the regulated organism;
- (iii) A description of the life cycle, biology, and ecology of the regulated organism;
- (iv) Whether the regulated organism has been genetically modified (if so, include a description of the genetic modification);
- (v) The established range of the regulated organism in the United States;
- (vi) Whether the regulated organism has been released into the environment in the area or areas of the United States for which the exemption is being

requested and, if so, the location and date of the release;

(vii) A description of all testing and review that has been conducted to assess the effects of the regulated organism on the environment;

(viii) The effect of the regulated organism on the environment in its established range;

(ix) The host specificity of the regulated organism under both artificial and natural conditions;

(x) References to any published and unpublished documents that support the information required by paragraphs (b)(1)(ii) through (b)(1)(ix) of this section. If available to the applicant, copies of any unpublished referenced documents must be attached to the application; and

(xi) A list of at least three universities, museums, scientific societies, or other organizations that maintain collections of organisms to which specimens of the regulated organism have been submitted, and the identification numbers assigned to the specimens.

(2) Within 30 days of receiving the request for exemption from regulation under this part, APHIS will review the request to determine whether the request contains all the information required by this section. If the request contains all of the information required by this section, APHIS will notify the person requesting the exemption of the date that the request was received, which will be the commencement date of a 120-day review period for requests for exemption. If the request does not contain all of the information required by this section, APHIS will advise the person submitting the request for an exemption of the additional information that must be received by the Administrator to complete the request for an exemption. APHIS will commence the review period upon receipt of the additional information, if, with the addition of that information, the request contains all of the information required by the section.

(3) If, based upon its review of the request, APHIS concludes that exempting the regulated organism from regulation under this part would not present a significant plant pest risk, APHIS will prepare a notice of proposed rulemaking for publication in the **Federal Register** proposing to add the organism to the list in paragraph (d) of this section of nonindigenous organisms exempt from regulation under this part.

(4) If, based upon its review of the request, APHIS is unable to conclude that exempting the regulated organism from regulation would not present a significant plant pest risk, the request for an exemption from regulation under

this part will be denied. The person requesting the exemption will be informed, in writing, of the denial and the reasons for APHIS' inability to find that exempting the regulated organism from regulation under this part would not present a significant plant pest risk. Any person whose request has been denied may appeal the decision, in writing, to the Administrator within 10 days of receiving the written notification of the denial. The appeal must state all of the facts and reasons upon which the person relies to show

that the request was wrongfully denied. The Administrator will grant or deny the appeal, in writing, stating the reasons for the denial as promptly as circumstances allow. If there is a conflict as to any material fact and the person whose request was denied requests a hearing, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(c) If, absent any request from the public, APHIS concludes that exempting any nonindigenous organism

from regulation would not present a significant plant pest risk, APHIS will prepare a notice of proposed rulemaking for publication in the **Federal Register** proposing to add the organism to the list in paragraph (d) of this section of nonindigenous organisms exempted from regulation under this part.

(d) *Exempted nonindigenous organisms.* The following nonindigenous organisms may be introduced without restriction under this part into the area or areas of the United States specified:

Class	Order	Family	Scientific or common name	Where exempt <sup>1</sup>
Arachnida .....	Scorpiones .....	.....	scorpions .....	(1)
Arachnida .....	Pseudoscorpiones .....	.....	pseudoscorpions .....	(1)
Arachnida .....	Solfugae .....	.....	windscorpions .....	(1)
Arachnida .....	Amblypygi .....	.....	tailless whipscorpions .....	(1)
Arachnida .....	Opiliones .....	.....	daddy-longlegs, harvestmen .....	(1)
Arachnida .....	Aranae .....	Theraphosidae .....	tarantulas .....	(1)
Insecta .....	Blattodea .....	.....	cockroaches .....	(1)
Insecta .....	Diptera .....	Culicidae .....	mosquitoes .....	(1)
Insecta .....	Diptera .....	Muscidae .....	<i>Musca domestica</i> .....	(1)
Insecta .....	Diptera .....	Drosophilidae .....	<i>Drosophila melanogaster</i> .....	(1)
Chilopoda .....	.....	.....	centipedes .....	(1)
Diploda .....	.....	.....	millipedes .....	(1)

<sup>1</sup> Areas of exemption are as follows: (1) The entire United States; (2) The continental United States (the conterminous 48 States and Alaska); (3) Hawaii; (4) Puerto Rico; (5) The Northern Mariana Islands; (6) Any other U.S. territory or possession.

**§ 335.6 Conditions for the introduction of regulated organisms.**

(a) *Importation.* A regulated organism may be imported into the United States only if:

- (1) The regulated organism is accompanied by a permit issued in accordance with § 335.4.
- (2) The regulated organism is imported through a port of first arrival designated by an asterisk in § 319.37-14(b) of this chapter or is mailed to APHIS at a port of first arrival designated by an asterisk in § 319.37-14(b) of this chapter;
- (3) Following its arrival at the port of first arrival, the regulated organism is not moved to any destination other than the destination listed on the permit;
- (4) The regulated organism is moved in a container that meets the requirements of § 335.8;
- (5) The container in which the regulated organism is being moved remains unopened until its arrival at the destination specified on the permit;
- (6) The regulated organism is not accompanied by any other organism or article, except as specified on the permit;
- (7) The outside of the container in which the regulated organism is being imported bears a label issued by APHIS;
- (8) The outside of the container in which the regulated organism is being moved accurately identifies the

regulated organism, the person to whom the permit was issued, the destination of the regulated organism, the return address of the sender of the regulated organism, and the number of the permit authorizing the importation;

(9) The person to whom the permit has been issued agrees to notify the Administrator of:

- (i) The accidental or unauthorized release into the environment of the regulated organism, immediately after the accidental or unauthorized release into the environment occurs; and
  - (ii) Any characteristics of the regulated organism that are substantially different from those listed in the application for a permit, no later than 5 days after identifying the characteristics;
- (10) The person to whom the permit has been issued agrees to present the regulated organism or any material accompanying the regulated organism to the Administrator for destruction, disposal, or the remedial measures the Administrator determines necessary to prevent the spread of plant pests, and to allow the Administrator to destroy, dispose of, or apply remedial measures to the regulated organism or any material accompanying the regulated organism if the Administrator determines that such action is necessary to prevent the spread of plant pests; and

(11) The regulated organism is imported in accordance with any other conditions specified on the permit.

(b) *Interstate movement.* A regulated organism may be moved interstate only if:

- (1) The regulated organism is accompanied by a permit issued in accordance with § 335.4.
- (2) The regulated organism is not moved to any destination other than the destination specified on the permit;
- (3) The regulated organism is moved in a container that meets the requirements of § 335.8;
- (4) The container in which the regulated organism is being moved remains unopened until its arrival at the destination specified on the permit;
- (5) The regulated organism is not accompanied by any other organism or article, except as specified on the permit;
- (6) The outside of the container in which the regulated organism is being moved identifies the regulated organism, the person to whom the permit was issued, the destination of the regulated organism, the return address of the sender of the regulated organism, and the number of the permit authorizing the interstate movement; and

(7) The person to whom the permit has been issued agrees to notify the Administrator of:

(i) The accidental or unauthorized release into the environment of the regulated organism, immediately after the accidental or unauthorized release into the environment occurs; and

(ii) Any characteristics of the regulated organism that are substantially different from those listed in the application for a permit, no later than 5 days after identifying the characteristics;

(8) The person to whom the permit has been issued agrees to present the regulated organism or any material accompanying the regulated organism to the Administrator for destruction, disposal, or the remedial measures the Administrator determines necessary to prevent the spread of plant pests, and to allow the Administrator to destroy, dispose of, or apply remedial measures to the regulated organism or any material accompanying the regulated organism if the Administrator determines that such action is necessary to prevent the spread of plant pests; and

(9) The regulated organism is moved interstate in accordance with any other conditions specified on the permit.

(c) *Release into the environment.* A regulated organism may be released into the environment only if:

(1) The release of the regulated organism into the environment is authorized by a permit issued in accordance with § 335.4;

(2) The person to whom the permit has been issued agrees to notify the Administrator of:

(i) The accidental or unauthorized release into the environment of the regulated organism, immediately after the accidental or unauthorized release into the environment occurs; and

(ii) Any characteristics of the regulated organism that are substantially different from those listed in the application for a permit, no later than 5 days after identifying the characteristics;

(3) The person to whom the permit has been issued agrees to present the regulated organism or any material accompanying the regulated organism to the Administrator for destruction, disposal, or the remedial measures the Administrator determines necessary to prevent the spread of plant pests, and to allow the Administrator to destroy, dispose of, or apply remedial measures to the regulated organism or any material accompanying the regulated organism if the Administrator determines that such action is necessary to prevent the spread of plant pests;

(4) Specimens of the regulated organism have been submitted to, and accepted into, the collections of at least

three universities, museums, scientific societies, or other organizations that maintain collections of organisms, and the identification numbers assigned to the specimens have been provided to APHIS; and

(5) The regulated organism is released into the environment in accordance with the conditions specified on the permit.

#### § 335.7 Facilities for the containment of regulated organisms.

(a) The Administrator will approve the use of a facility for the containment of a regulated organism only if:

(1) The facility's physical structure possesses adequate water, air, and waste handling systems, as well as adequate entryways, windows, and facility structure to contain the regulated organism and prevent the unauthorized entry of organisms and people;

(2) The facility has procedural safeguards and is operated in a manner that will prevent the escape of a regulated organism and will prevent the unauthorized entry of organisms and people;

(3) The facility has a means of inactivating or sterilizing the regulated organism and any host material, containers, or other material used for the regulated organism;

(4) The facility and its operation meet any other conditions the Administrator deems necessary to prevent the escape of a regulated organism and will prevent the unauthorized entry of organisms and people;

(5) During the time that a regulated organism is held in the facility, the operator of the facility maintains records that identify the regulated organism, the person from whom the regulated organism was received, the date the regulated organism was received at the facility, and the disposition of the regulated organism; and

(6) During normal business hours, an APHIS inspector is allowed to inspect and copy the records required by paragraph (a)(5) of this section.

(b) [Reserved]

#### § 335.8 Container requirements for the movement of regulated organisms.

(a) *General requirements.* A regulated organism shall not be imported or moved interstate unless the regulated organism and any material accompanying the regulated organism are enclosed in a container that complies with paragraph (b) of this section, unless a variance has been granted in accordance with paragraph (c) of this section.

(b) *Container requirements.* (1) *Plants and plant parts.* All plants or plant

parts, except seeds and cells, must be enclosed in a sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container, and then enclosed in a sturdy, sealed, outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds must be enclosed in a sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container. The sealed plastic bag or equivalent leakproof container must then be enclosed within a second sealed plastic bag of at least 0.1270 mm (5 mil) thickness or in an equivalent leakproof container. Each plastic bag or equivalent leakproof container must be independently capable of preventing the seeds from escaping the container. Each set of containers must be enclosed in a sturdy outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Microorganisms.* All microorganisms, such as fungi, bacteria, nematodes, or cells, must be enclosed in a container as specified in paragraph (b)(3)(i) or (b)(3)(ii) of this section:

(i) *Volume not exceeding 50 mL.* Microorganisms not exceeding 50 mL in volume must be enclosed in a durable, watertight primary container, which must be enclosed in a second durable, watertight container (secondary container). Several primary containers may be enclosed in a single secondary container if the total volume of all the primary containers enclosed in a single secondary container does not exceed 50 mL. The space at the top, bottom, and sides between the primary and secondary containers must contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s). The secondary container must then be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 mL.* Microorganisms that exceed a volume of 50 mL must comply with requirements in paragraph (b)(3)(i) of this section. In addition, a shock-absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, must be placed at the top, bottom, and sides between the secondary container and the outer container. Single primary containers may not contain more than 1,000 mL of material. However, two or more primary containers whose combined volumes do not exceed 1,000 mL may be enclosed in a single secondary container. The maximum

amount of microorganisms that may be enclosed within a single outer container shall not exceed 4,000 mL.

(iii) *Dry ice*. If dry ice is used as a refrigerant, it must be placed between the secondary container and the outer container. The shock-absorbing material must be placed so that the secondary container does not become loose inside the outer container as the dry ice sublimates.

(4) *Arthropods*. Insects, mites, or other arthropods must be enclosed in a container as specified in this paragraph or in paragraph (b)(3) of this section. Arthropods (any life stage) must be enclosed in a primary container (insulated vacuum container, metal, or plastic) and the container must be sealed to prevent escape of the arthropods. The primary container must be enclosed in a secondary container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be enclosed in the secondary container; and sufficient packing material must be added around the primary container to prevent movement of the primary container within the secondary container. The secondary container must be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other organisms*. Any organism not covered in paragraph (b)(1), (b)(2), or (b)(4) of this section that does not require continuous access to atmospheric oxygen must be enclosed in a container as specified in paragraph (b)(3) or (b)(4) of this section. Any organism that is not a plant and that requires continuous access to atmospheric oxygen must be enclosed in a primary container constructed with a sturdy, crush-proof frame of wood, metal, or other material of equivalent strength, surrounded by mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest

organism in the container, with the edges and seams of the mesh or netting sealed to prevent the escape of organisms. Each primary container must be enclosed in a larger secondary container constructed of wood, metal, or other material of equivalent strength. The primary and secondary containers must be enclosed in an outer container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer container must retain sufficient strength to prevent crushing of the primary and secondary containers.

(c) *Request for a variance from container requirements*. If the person applying for a permit for the introduction of a regulated organism believes that the container requirements in paragraph (b) of this section are inappropriate for the importation or interstate movement of a regulated organism due to unique circumstances (such as the nature, volume, or life stage of the regulated organism), that person may request a variance from the container requirements in paragraph (b) of this section when applying for a permit. The request for a variance under this section must consist of a written statement describing why the applicable container requirements in paragraph (b) of this section are inappropriate for the regulated organism that the person proposes to move, and what container requirements the person would use in lieu of the applicable container requirements of paragraph (b) of this section. Prior to the issuance of a permit, APHIS will advise the person as to the disposition of his or her request for a variance from the container requirements in paragraph (b) of this section. If APHIS has granted the variance request, a permit will be issued if APHIS had determined from its review of the permit application that the

regulated organism can be introduced without risk of plant pest dissemination. Any person who has been denied a variance from the container requirements in paragraph (b) of this section may appeal the decision in writing to the Administrator within 10 days after receiving the written notification of the denial. The appeal must state all of the facts and reasons upon which the person relies to show that the variance was wrongfully denied. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact and the person denied a variance requests a hearing, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. No permit will be issued until such time as the appeal is resolved and the applicant has agreed to abide by APHIS' decision.

#### § 335.9 Costs and charges.

Unless a user fee is payable under § 354.3 of this chapter, the services of an APHIS inspector during regularly assigned hours of duty and at the usual places of duty will be furnished without cost. The U.S. Department of Agriculture's provisions relating to overtime charges for an APHIS inspector's services are set forth in part 354 of this chapter. The U.S. Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with this part, other than for the services of the APHIS inspector.

Done in Washington, DC, this 23rd day of January 1995.

**Lonnie J. King,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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